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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/803,266	03/09/2001	Arthur A. Alfaro	285-148	7075

7590 03/14/2005

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EXAMINER

PRIDDY, MICHAEL B

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 03/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 09/803,266	Applicant(s) ALFARO ET AL.	
	Examiner Michael B Priddy	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-17, 19-21 and 23-37 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 9-11, 19, 30, 32, 33 and 37 is/are allowed.
- 6) ☒ Claim(s) 3-8, 12-17, 23-26, 28, 29, 31 and 34-36 is/are rejected.
- 7) ☒ Claim(s) 20, 21 and 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The indicated allowability of some claims has been withdrawn in view of a new interpretation of the reference to Crozet. Rejections based on the new interpretation follows. The Examiner sincerely regrets any inconvenience to Applicant or Applicant's representative.

Claim Objections

Claims 20 and 21 are objected to because of the following informalities: in line 1, "18" should be --19--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "the threads on the inner surface of the C-shaped ring" in line 3. There is insufficient antecedent basis for this limitation in the claim since claim 3 provides basis only for a "threaded portion".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5, 8, 24-26 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Crozet (AU 744371). Crozet teaches a two-part intervertebral spacer comprising: a first component 10 having upper 104 and lower 104' vertebral engaging surfaces and a thickness between the upper 104 and lower 104' surfaces, the first component 10 being a C-shaped ring at least a portion of an inner surface of which is threaded 108; and a cylindrical locking element 20 engagable within C-shaped ring 10, said locking element 20 having a height greater than the thickness of the C-shaped ring 20 and having threads 22 on an outer surface thereof, which threads 22 are engagable with threaded portion (108a) on the inner surface of the C-shaped ring 10; wherein the cylindrical locking element 20 comprises stainless steel or titanium (lines 20-22 of page 27) and includes a throughbore 34. Concerning the method steps recited by claim 31, it is noted that Crozet discloses this method of implantation in line 3 of page 15 through line 5 of page 16.

Claim Rejections - 35 USC § 103

Claims 6, 7, 12-17, 23, 28, 29 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet in view of Boyce et al. (U.S. 6,294,041). Crozet

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teaches a two-part intervertebral spacer comprising: a first component 10 having upper 104 and lower 104' vertebral engaging surfaces and a thickness between the upper 104 and lower 104' surfaces, the first component 10 being a C-shaped ring at least a portion of an inner surface of which is threaded 108, wherein the thickness of the C-shaped ring varies from a proximal end to the distal end to form a taper (viewable in Fig. 43); and a cylindrical locking element 20 engagable within C-shaped ring 10, said locking element 20 having a height greater than the thickness of the C-shaped ring 20 and having threads 22 on an outer surface thereof, which threads 22 are engagable with threaded portion (108a) on the inner surface of the C-shaped ring, wherein said locking element further comprises a throughbore 34 and which is tapped to allow for the receipt of an insertion instrument. Hence Crozet teaches all of the limitations of the present invention except the spacer comprising bone wherein at least one of the upper and lower vertebral engaging surfaces are wholly or partially surface demineralized.

Boyce et al. teaches a method for osteoimplant manufacture the inventive concept of which includes formation of an implant 40 implantable between adjacent vertebrae as shown in Fig. 4. In lines 54-57 of column 7, Boyce et al. disclose production of an implant having a fully or partially demineralized outer surface which yields surface-exposed collagen capable of promoting and/or accelerating new bone growth (col. 2, lines 1-6). It would have been obvious to one of ordinary skill in the art at the time of the present invention to form the spacer of Crozet of bone and such that at least one of the upper or lower surfaces were partially surface demineralized so that new bone growth was promoted and/or accelerated upon implantation of the ring.

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Concerning the limitations of claim 36 requiring "the inner surface of the C-shaped ring is threaded after insertion of the spacer and simultaneously with formation of threads in adjacent vertebral endplates", it is noted that the device of the combination taught by Crozet in view of Boyce et al., appears to be substantially identical to the device claimed, although produced by a different process, therefore the burden is upon the Applicant to come forward with evidence establishing an unobvious difference between the two. In re Marosi, 218 USPQ 289 (Fed. Cir. 1983).

Allowable Subject Matter

Claims 9-11, 19, 30, 32, 33 and 37 are allowed.

Claim 27 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 20 and 21 would be allowable if rewritten to overcome the objection set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record teaches or fairly suggests an intervertebral implant (spacer) as set forth in claims 9, 19 and 30 including "an intact ring" wherein an intact ring has been interpreted as an annular-shaped object in which any bore formed

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therein and in the plane of the annulus does not extend through both the exterior surface of the annulus and the interior surface defined by the central opening.

Nor does the prior art of record teach or fairly suggest the intervertebral spacer of claim 27 wherein at least one of the first component and the second component is of substantially closed structure and is formed from bone.

Nor of the prior art of record teaches or fairly suggests the method of claim 32 and, in particular, the step of "prior to engaging, threads are simultaneously formed on an inner surface of the bore and at least one endplate of the adjacent vertebrae".

Nor does the prior art of record teach or fairly suggest the method of claim 33 and, in particular including the step of "the bore defined in the ring is formed after the step of positioning the ring."

Finally, the prior art of record does not teach or fairly suggest a two-part intervertebral spacer as defined by claim 37 wherein upper and lower surfaces of a C-shaped ring "possess both concave and convex curvatures designed to conform to adjacent vertebrae in order to maximize surface contact between the spacer and the adjacent vertebrae."

Conclusion

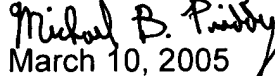
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael B. Priddy whose telephone number is (571) 272-4717. The examiner can normally be reached on Mon.-Fri. 8 a.m. - 5 p.m..


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael B. Priddy


March 10, 2005


KEVIN SHAVER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700